REMARKS

Reconsideration and allowance of this application are respectfully requested in light of the foregoing amendments and the following remarks.

Claim Status

Claims 1-8 were presented in the originally filed application. New claims 9-14 were added. Claims 2, 3, 8-10, 12, and 13 are cancelled. Claims 5, 6, and 14 were amended. Claims 1, 4-7, 11, and 14 are pending. No new matter was added.

§112 Rejection

Claims 1, 3-7, 11, and 14 stand rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written restriction requirement. Applicant traverses.

The Examiner alleges that the experimental conditions used for obtaining the X-ray diffraction data on which claims 1, 3-7, 11, and 14 are based is not described in the specification. The Examiner alleges that experimental conditions such as Cu K_α, the instrument brand name, and instrument calibration parameters are not contained within the specification. The Examiner is clearly mistaken. The paragraph immediately preceding the examples plainly states, "The X-ray diffraction spectra were measured on

a Phillips ADP1700 power diffractometer with a Cu irradiation of $K_{\alpha 1}$ = 0.15406 nm and $K_{\alpha 2}$= 0.15444 and a voltage of 40 kV." (Specification, Page 5, Lines 25-26). By providing the instrument (Phillips ADP1700 power diffractometer), the appropriate CU irradiation settings, and instrument calibration parameters, a person of ordinary skill in the art would have the ability to duplicate the findings provided in the instant specification. Looking to M.P.E.P. 2163 it states:

> An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

Clearly, the language contained in the specification of the instant invention describes all of the experimental conditions used for obtaining the X-ray diffraction data on which claims 1,

3-7, 11, and 14 are based in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner then claims that the specification is inadequate in that it fails to provide raw data of the X-ray powder diffraction spectrum of the δ crystalline form of perindopril erbumine because such a spectrum would be necessary for demonstrating the quality of the X-ray diffraction data. Again, the Applicant must respectfully disagree. Raw X-ray diffraction data **is not** required in order to demonstrate that Applicant was in possession of the instant invention at the time the application was filed. To the contrary, a list of 2-theta angles or d-spacings is more that sufficient to characterize a polymorph, as they are in the instant application, in order to prove that Applicant was in possession of the invention claimed in the instant application. (See M.P.E.P. 2163 above).

The Examiner then goes on to claim that the instant specification is inadequate in that it fails to provide TGA and DSC data to support that the δ crystalline form is an anhydrate form, and not a hydrate form. Again, Applicant must respectfully disagree with this argument. There is no claim

anywhere in the instant application that the δ crystalline form is anhydrous. To the contrary, it is clearly stated in the instant specification that δ crystalline form perindopril erbumine may be obtained by using "tert.-butyl methyl ether containing a certain amount of water." (Specification, Page 4, Lines 18-21). Clearly, based on the information disclosed in the instant specification, no TGA or DSC data is required in order to prove that Applicant was in possession of the claimed invention. In light of the information contained in the instant specification, Applicant respectfully requests that the rejection of independent claim 1 and dependent claims 3-7, 11, and 14 be removed and the claims allowed.

Claim 6 stands rejected under 35 U.S.C. §112 first paragraph as failing to comply with the written restriction requirement, and more specifically, as being beyond the scope taught in the instant specification. Applicant traverses.

Applicant has amended the language of claim 6 in order to more clearly define the claim. More specifically, the language of claim 6 now relates to a "composition according to claim 5 for use as ACE inhibitor in the treatment of hypertension, stable coronary artery disease, and heart failure." This language is more in line with what the Examiner pointed out as

being the state of the prior are. In light of the amendment to claim 6, Applicant respectfully requests the rejection to claim 6 be removed and the claim allowed.

Claims 5-6, 11, and 14 stand rejected under 35 U.S.C. §112 first paragraph as failing to comply with the written restriction requirement. Applicant traverses.

The Examiner claims that in order to mix a pharmaceutical with an excipient, it is necessary to dissolve a pharmaceutical compound with exipients in a solution, and remove the solvent to make dry powder, citing U.S. Patent Application No. 2007/0178166 hereinafter Bernstein). The Examiner is clearly mistaken.

Bernstein does not state that in order to mix a pharmaceutical with an excipient, it is necessary to dissolve a pharmaceutical compound with exipients in a solution, and remove the solvent to make dry powder. In fact, Bernstein is directed toward very specific methods "for making bended particle or microparticle pharmaceutical formulations that have high content uniformity and that disperse well upon pulmonary or nasal administration." ((Bernstein, Paragraph 7, Lines 1-5). In the formulation process, it is not necessary to dissolve the active principle ingredient with excipients into a solution. For

example, the active principle ingredient may be dry mixed with one or more excipients prior to being compressed into a tablet. Bernstein itself acknowledges that "certain desirable excipient materials are difficult to mill or blend with pharmaceutical agent microparticles," and lists possible examples including liquid and waxy excipients. (Bernstein, Paragraph 6, Lines 1-5). The language selected by Bernstein clearly indicates that while certain excipient materials may be difficult to mill or blend, other excipient materials are readily millable and blendable in dry form. Bernstein describes the blending of two dry particles, including one excipient to form a powder blend and makes no mention of first dissolving either substance prior to mixing. (Bernstein, Paragraph 27, Lines 9-21).

Additionally, Applicant has amended claims 5, 6, and 14 to "solid pharmaceutical compositions" in order to avoid claiming pharmaceutical compositions wherein the active principle is in solution. In light of the arguments presented above and the amendments to the claims, Applicant respectfully requests that the rejection of claims 5-6, 11, and 14 be removed and the claims allowed.

Reconsideration and allowance of this application is respectfully requested.

Respectfully submitted,

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